

REMARKS

STATUS OF THE CLAIMS

Claims 1, 3-4, 9-11, 15-28 and 38-41 are pending as shown in the Amendment After Final filed July 6, 2005 and which claim amendments were entered following the filing of a request for continued examination (RCE) on August 25, 2005.

REJECTIONS WITHDRAWN

Applicants note with appreciation that the rejections under 35 U.S.C. § 103 based on WO 00/44287 (hereinafter “Krall”) in view of U.S. Patent No. 6,160,025 to Slaikeu have been withdrawn.

35 U.S.C. § 103

Claims 1, 3-4, 9-11, 15-28 and 39-41 were rejected under 35 U.S.C. § 103 as allegedly obvious over Krall in view of U.S. Patent No. 6,203,779 (hereinafter “Ricci”). (Office Action, pages 3-5). Claims 1, 3-4, 9-11, 15-28 and 38-41 were rejected under 35 U.S.C. § 103 as allegedly over Krall in view of Ricci and further in view of U.S. Patent No. 4,997,861 (hereinafter “Hechenberger”). In support of both rejections, the Office Action states, in part, at pages 4-5 (emphasis added):

Krall’s composition only lacks a polymeric non-cyanoacrylate rheology modifying agent that has an average molecule weight greater than 200,000.

Ricci describes embolic compositions comprising a polymer which falls within the scope of the instantly claimed non-cyanoacrylate rheology modifying agents. The cellulosic polymers of Ricci have an average molecular weight of **about** 200,000. (see col 5, lines 33-35). Ricci explicitly states that adjustment of the viscosity of the composition can be readily achieved by mere adjustment of the molecular weight of the polymer in the compositions. (see col 5, lines 39-41). Therefore, for purposes of adjusting the viscosity of an embolic composition, all biocompatible polymers described by Ricci are functional equivalents.

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flow logically from their having been individually taught in the art [citing *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980)].

Because Krall and Ricci do not teach or suggest the claimed compositions, Applicants traverse the rejection.

In order to establish a *prima facie* case of obviousness, the burden is on the Office to show that the proposed combination of references teaches or suggests all the limitations and that there is a motivation to combine the references as set forth in the rejection. *See, e.g., M.P.E.P. §§ 2142-2143.*

In the instant case, the proposed combination of Krall and Ricci does not teach or suggest all the limitations of the claims or provide the motivation to make the combination.

First and foremost, Krall and Ricci do not teach or suggest polymeric rheology modifying agents having an average molecular weight **greater than** 200,000, as required by the pending claims. (See, claim 1, lines 5-6). Indeed, as acknowledged by the Office, Krall teaches nothing about such rheology modifying agents whatsoever.

For its part, Ricci does not teach or suggest cellulosic polymers having an average molecular weight of **greater than** 200,000. Rather, Ricci's teaches that 200,000 is the maximum average molecular weight of such cellulose diacetate polymers (col. 5, lines 23 to 35 of Ricci):

Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. Cellulose diacetate polymers are either commercially available or can be prepared by art recognized procedures. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. The weight average molecular weight of the cellulose diacetate composition, as determined by gel permeation chromatography, is preferably from about 50,000 to 200,000 and more preferably from about 100,000 to about 180,000.

Thus, neither Ricci nor Krall teach all the elements of the pending claims, namely a composition comprising a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight **greater than** 200,000.

In addition to failing to teach or suggest all the claim limitations, there is no motivation in Krall or Ricci to make the combination suggested. The law is well settled that references must suggest the desirability of arriving at the claimed subject matter. *See, e.g., Amgen, Inc. v.*

Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991) stating that "hindsight is not a justifiable basis on which to find that the ultimate achievement of a long sought and difficult scientific goal was obvious;" *In re Laskowski*, 10 USPQ2d 1397, 1399 (Fed. Cir. 1989) stating that "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification"; and *In re Fulton*, 391 F.3d 1195 (Fed. Cir. 2004) stating that "[t]he question is whether there is something in the prior art as a whole to suggest the desirability."

Thus, even assuming that Krall and Ricci did teach all the claim limitations (which they clearly do not), an obviousness rejection **cannot** be predicated on mere identification in a reference of individual components of claimed limitations. In this regard, the Federal Circuit has consistently reversed a finding of obviousness, even when all claimed elements are individually present in the references. *See, e.g., In re Kotzab* 217 F.3d 1365, 55 USPQ2d 1313, 1317 (CAFC 2000, emphasis added):

While the test for establishing an implicit teaching, motivation or suggestion is what the combination of these two statements [in the reference] would have suggested to those of ordinary skill in the art, the two statements cannot be viewed in the abstract. Rather, they must be considered in the context of the teaching of the entire reference. Further, a rejection **cannot** be predicated on the mere identification [in the reference] of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

Virtually all inventions are combinations of elements that can be individually identified in multiple references. *See, e.g., In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) and *In re Lee* noting that the Office cannot rely on a high level of skill in the art to overcome the differences between the selected elements in the references or to provide the necessary motivation.

In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), cited on page 5 of the Office Action, related to process claims for preparing a spray-dried detergent composition from two known compositions. To the extent that process claims are even relevant to the case at hand, Applicants note that the holding in *Kerkhoven* that the motivation to sustain an obviousness rejection "flows logically from their having been individually taught in the prior art" relates only to situations in

which a claimed process combines delivery of two known compositions and, moreover, wherein the claimed process delivers the known compositions in the same way they are delivered in the cited references. Indeed, the CCPA held in *Kerkhoven* that claims to methods of simultaneously spray-drying the two known compositions were in fact non-obvious in view of prior art disclosing delivery the compositions separately. *In re Kerkhoven*, 205 USPQ at 1073-1074. Accordingly, *Kerkhoven* is not relevant to the pending compositions claims, which are drawn to novel and non-obvious combinations of elements not taught in Krall, Ricci or Hechenberger.

To reiterate, the requirement is not whether each claimed element can be identified individually in a reference (which in this case they cannot) but, rather, whether the Examiner can show “reasons that the skilled artisan, confronted with the same problem as the inventor, and with no knowledge of the claimed invention, would select the elements from the cited prior art reference for combination in the manner claimed.” *In re Rouffet*, 47 USPQ2d at 1458.

In the pending case, the Office has not met this burden. There is no suggestion in Krall or Ricci to combine matrix-forming components and polymeric non-cyanoacrylate rheology modifying agents as claimed. For the reasons noted above with respect to *In re Kerkhoven*, the motivation to combine cannot derive from “use for the same purpose.”

Nor can the motivation derive from “optimizing viscosity.” (Office Action, page 5). There is nothing in Krall regarding polymeric non-cyanoacrylate rheology modifying agents and nothing in Ricci that suggests making a combination with a matrix-forming cyanoacrylate. To the contrary, Ricci teaches that cyanoacrylates are “biocompatible prepolymers” (defined at col. 6, lines 57-67 of Ricci) while cellulose diacetate polymers are “biocompatible polymers” (defined at col. 5, line 4 to col. 6, line 9 of Ricci). Ricci draws a clear distinction between cyanoacrylate prepolymers and polymers such as cellulose diacetate and unambiguously teaches that they are used separately (Ricci, Abstract and col. 1, lines 11-14, emphasis added):

Sealing of endoleaks is achieved by injection of either a biocompatible polymer or prepolymer fluid composition into the endoleak which composition in situ solidifies to seal the leak.

Ricci’s teaching that cyanoacrylates and cellulose diacetates are distinct compositions that are to be used in the alternative is also mirrored in the claims of this patent – claim 1 is

drawn to a fluid composition generally, claims 2-12 specify that the fluid composition is a biocompatible polymer; while claims 13-14 specify that the fluid composition include a biocompatible prepolymer. Simply put, there is nothing in Ricci that teaches or suggest combining prepolymers (*e.g.*, cyanoacrylate) in the same composition as polymers (*e.g.*, cellulose diacetate) and, indeed, this reference **teaches away** from making a composition containing both cyanoacrylate prepolymers and cellulose diacetate polymers. Accordingly, there is no motivation to combine Ricci with Krall and a *prima facie* case of obviousness cannot be established.

In sum, Krall and Ricci do **not** teach or suggest all the elements of the claims. Moreover, because Ricci clearly teaches that cyanoacrylates and cellulose diacetate are separate compositions, the skilled artisan would have no motivation to make the combination set forth by the Office. Hechenberger does not in any way make up for the deficiencies of Krall and Ricci. Therefore, without the benefit of Appellants' disclosure, a skilled artisan would have had no motivation to combine a matrix-forming component (alkyl cyanoacrylate monomers, a stabilizer and a plasticizer) with a solid aggregate material and a polymeric non-cyanoacrylate rheology-modifying agent having a molecular weight greater than 200,000. The references do not teach all the claimed elements and the motivation to combine the references as set forth in the rejection is not present in the references themselves. Accordingly, the rejections under 35 U.S.C. § 103 should be withdrawn.

CONCLUSION

Applicants believe that the claimed subject matter is now in condition for allowance and early notification to that effect is respectfully requested. If any issues remain to be addressed, the Examiner is encouraged to telephone the undersigned.

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